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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,024	03/22/2007	Steen Brummerstedt Iversen	PLOUG17.002APC	6964

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EXAMINER
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PENNY, TABATHA L

ART UNIT	PAPER NUMBER
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1712

NOTIFICATION DATE	DELIVERY MODE
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07/13/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/583,024	<b>Applicant(s)</b> IVERSEN ET AL.	
	<b>Examiner</b> TABATHA PENNY	<b>Art Unit</b> 1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 148-219 is/are pending in the application.
- 4a) Of the above claim(s) 158-219 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 148-157 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Receipt is acknowledged of the remarks and amendments, filed 4/27/2010, in response to the non-final office action, dated 12/03/2009.
2. Claims 148-219 are pending. Claims 158-219 are withdrawn. Claims 148, 150-152, and 154-155 are amended. No new matter has been added.

### *Specification*

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. **It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.**

4. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) **if a process, the steps.**

Extensive mechanical and design details of apparatus should not be given.

5. The abstract of the disclosure is objected to because of improper language and content. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 148-149, 153, and 156 rejected under 35 U.S.C. 102(b) as being anticipated by WATKINS et al. (US 5,789,027).
8. **Regarding claim 148**, WATKINS et al. discloses a method of depositing a film of material on the surface of a substrate, i.e. producing a fine particle material, comprising: dissolving a precursor of the material into a supercritical solvent (abstract), i.e. at least one of the fluids being in a supercritical state before or after being introduced into said vessel, in a vessel (col. 8 line 15), i.e. introducing one or more substances contained in one or more fluids into a vessel by introducing said fluids into the vessel; exposing the

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substrate to the solution under conditions at which the precursor is stable (abstract), i.e. said vessel containing one or more sections comprising a material; initiating a chemical reaction (abstract), i.e. wherein at least one of said substances undergoes a chemical reaction; wherein at least one of said substances undergoing a chemical reaction is an alkoxide (col. 7 lines 41-43); wherein said alkoxide comprises a metal (col. 7 lines 41-43); wherein the method further comprises: introducing into the reaction vessel at least one reaction reagent (abstract), i.e. initiator for said chemical reaction.

9. Watkins et al. further discloses the process is performed continuously wherein the supercritical solution and reaction reagent are continuously added to a reaction vessel containing multiple substrates as supercritical solution containing precursor decomposition products or unused reactants is continuously removed from the reaction vessel (col. 5 ln. 4-11). As Watkins et al. discloses continuous addition of the reaction reagent to the vessel, Watkins et al. inherently discloses addition of the reaction reagent, i.e. initiator, subsequent to the precipitation.

10. **Regarding claim 149**, WATKINS et al. does not appear to explicitly disclose the reactions are sol-gel reactions.

11. However, WATKINS et al. discloses the same reactants in the same reactions under the same process conditions as applicants' (col. 1 lines 53-62). Therefore, Watkins et al. inherently discloses the reactions are sol-gel reactions.

12. **Regarding claim 153**, WATKINS et al. discloses wherein at least one of said fluids being in a supercritical state is carbon dioxide (col. 6 lines 42-43).

13. **Regarding claim 156**, WATKINS et al. discloses wherein the fluid further comprises at least one co-solvent (col. 5 lines 58-61).

***Claim Rejections - 35 USC § 103***

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15. Claims 150-152, 154-155, and 157 are rejected under 35 U.S.C. 103(a) as being unpatentable over WATKINS et al. (US 5,789,027) in view of GUPTA et al. (US 2002/0000681).

16. **Regarding claim 150**, WATKINS et al. discloses the primary particles are 80-100 nanometers. “In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).” MPEP 2144.05.

17. **Regarding claim 151 and 152**, WATKINS et al. is silent as to the standard deviation of the size distribution of the primary particles.

18. However, GUPTA et al. discloses various particle sizes and standard deviations, such as 96 nm size with 43 nm standard deviation, or **45%** of the average size of the primary particles (para. [0131]); 30 nm size with **13 nm** standard deviation, or **43%** of the average size of the primary particles (para. [0133]); and 0.28 um size with 0.13 um standard deviation, or **46%** of the average size of the primary particles (para. [0139]). “In the case where the claimed ranges “overlap or lie inside ranges disclosed by the

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prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).” MPEP 2144.05.

19. At the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to include the particle size distribution, of GUPTA et al., with the method of WATKINS et al. in order to obtain an appropriate sized nanoparticle suitable for use in a particular industry (GUPTA et al. para. [0004]).

20. **Regarding claim 154**, WATKINS et al. discloses wherein the pressure of at least one of said fluids is in the range of 50-500 bar (col. 5 line 36). “In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).” MPEP 2144.05.

21. **Regarding claim 155**, WATKINS et al. discloses wherein the temperature in the vessel is maintained 100-250°C (col. 7 line 23). “In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).” MPEP 2144.05.

22. **Regarding claim 157**, WATKINS et al. further discloses precipitation is provided by a change of solubility which is due to expanding one of said fluids containing at least one of said substances in the vessel (col. 8 lines 15-20).

23. WATKINS et al. does not appear to explicitly disclose the change in solubility is due to an antisolvent present in the vessel.

24. However, GUPTA et al. discloses a method of precipitating micron or nanometer size particles wherein a dispersion containing the substance of interest is contacted with an antisolvent (para. [0004]). GUPTA et al. further discloses the method produces very small particles having a narrow size distribution (para. [0025]).

25. At the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the method of WATKINS et al. to include the antisolvent, as taught by GUPTA et al., in order to obtain very small particles having a narrow size distribution for use in designing drug delivery systems for controlled release and targeting in the pharmaceutical industry (para. [0006]).

### ***Response to Arguments***

26. Applicant's arguments, see amendments, filed 4/27/2010, with respect to the objection of the drawings have been fully considered and are persuasive. The objection of the drawings has been withdrawn.

27. Applicant's arguments, see amendments and remarks, filed 4/27/2010, with respect to the rejection of claims 150-152 and 154-155 under 35 U.S.C. 112 have been fully considered and are persuasive. The rejection of the claims has been withdrawn.

28. Applicant's amendment filed 4/27/2010 with respect to the rejection(s) of claim(s) 148-157 under 35 U.S.C. 103 have been fully considered but they are not persuasive. The amendment adds the limitation of introducing the initiator for the chemical reaction to the vessel subsequent to the precipitation. Watkins et al. discloses this limitation as



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discussed with regards to claim 148 above; therefore, the amendment does not patentably distinguish the claimed invention from the prior art.

### ***Conclusion***

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TABATHA PENNY whose telephone number is (571)270-5512. The examiner can normally be reached on Monday thru Friday 8:00am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Cleveland can be reached on (571)272-1418. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/tp/

/Michael Cleveland/  
Supervisory Patent Examiner, Art Unit 1712